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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,745	12/28/2001	Anne M. Pianca	AB-164U	3645
23845	7590	09/03/2004	EXAMINER	
ADVANCED BIONICS CORPORATION 25129 RYE CANYON ROAD VALENCIA, CA 91355			SCHAETZLE, KENNEDY	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 09/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/035,745

Applicant(s)

PIANCA ET AL.

Examiner

Kennedy Schaetzle

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 1-12 and 19-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/4/02.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION
Election/Restrictions

1. Applicant's election of the invention of Group II (claims 13-18) in the reply filed on June 21, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Wyatt et al. (Pat. No. 5,006,122).

Wyatt et al. disclose the use of a first cannula, a second cannula slidable supported within the first cannula and capable of extending beyond the proximal and distal end of the first cannula. A lead is considered insertable through the second cannula by virtue of the fact that a stylet can be inserted.

While the preamble was considered, lacking any specific structural recitation in the claim body limiting the system to such use, the preamble was deemed insufficient to saliently distinguish over the apparatus of the prior art.

The "remains external to the body" recitation was also considered in regards to the first cannula, but lacking any specific structural recitation limiting the first cannula to such a position, statements relating to the relative positioning of structure with respect to the body fail to distinguish over the structure of the prior art. Apparatus claims must be distinguished from the prior art in terms of structure rather than function (see MPEP 2114).

Regarding the recitation of a lead being insertable through the second cannula, since practically any object similar to a stylet is *insertable* through the second cannula,

the examiner considers a lead of similar dimension to also be insertable. The applicants are not claiming the lead itself, but rather a lead introduction system for use with a lead.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

4. Claims 13, 15, 16 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Collins, Jr. (Pat. No. 4,886,065).

Regarding claims 13 and 16, the examiner considers element 12 to represent a first cannula (i.e., tube) held in a substantially fixed position external to the body as shown in Fig. 2. A second cannula 14 is slidably supported by the first cannula, with its proximal end and its distal end extending beyond the first cannula (see Fig. 2). A lead 15 is inserted through the second cannula. It should be noted that one can also consider element 13 to represent the first cannula, as the claim does not require that the entire length of the first cannula be external the body –simply that it be held in a position external the body. The examiner also considers the first cannula to be “substantially fixed” when held as shown in Fig. 2.

Concerning claim 15, the examiner considers electrode 10 to be a macroelectrode and included within the second cannula.

Concerning claim 18, since the applicant has neither defined what steps in the method involve “...using the second cannula as a macroelectrode...,” nor the structural relationship between the second cannula and the macroelectrode, the examiner will take the position that when the macroelectrode 10 is secured within the second cannula, the second cannula is used as a macroelectrode.

5. Claims 13-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Cosman (Pat. No. 4,565,200).

As shown in Figs. 3 or 4, Cosman employs a first cannula 1, a second cannula 28 slidable within the first cannula and extending beyond the distal and proximal end of the first cannula. A lead 19 is insertable within the second cannula. It should also be noted that one could consider elements 16 or 19 to constitute a second cannula (note

col. 3, lines 1-14), with the wire conductor connecting the distal electrode to the proximal end constituting a lead.

Regarding claims 14 and 17, Cosman discloses that the invention applies to stereotactic instruments (note col. 5, lines 32-36). An inherent property of a stereotactic device in addition to having a frame, is to hold medical instruments in steady fixed position to precisely and accurately position the instrument with respect to the body.

Regarding claims 15 and 18, the examiner considers the second cannula to contain macroelectrodes 19a and 19b.

Concerning claim 16, comments related to those given above in the rejection of claim 13 apply here as well. Once again the examiner wishes to point out that the step of holding a first cannula in a substantially fixed position external to the body does not require that the entire length of the cannula be external to the body –simply that it be held in a position external the body.

Conclusion


6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaezle whose telephone number is 703 308-2211. The examiner can normally be reached on 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-0851. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS
August 22, 2004


KENNEDY SCHAEZLE
PRIMARY EXAMINER